

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

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THE JOHNS HOPKINS UNIVERSITY, : CIVIL ACTION
A Maryland Corporation, :
BAXTER HEALTHCARE CORPORATION, :
A Delaware Corporation, :
and BECTON DICKINSON AND :
COMPANY, a New Jersey :
Corporation, :

Plaintiffs :

v. :

CELLPRO, A Delaware :
Corporation, :

Defendant :

NO. 94-105 (RRM)

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Wilmington, Delaware
Wednesday, April 30, 1997
10:30 o'clock, a.m.

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BEFORE: HONORABLE RODERICK R. McKELVIE, U.S.D.C.J.

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APPEARANCES:

POTTER, ANDERSON & CORROON
BY: WILLIAM J. MARSDEN, JR., ESQ.

Counsel for Plaintiffs

Leonard A. Dibbs and
Valerie J. Gunning,
Official Court Reporters

<p>1 APPEARANCES (Continued):</p> <p>2</p> <p>3 FOLEY, HOAG & ELIOT BY: DONALD R. KARR, ESQ. and 4 PETER B. ELLIS ESQ. (Boston, Massachusetts)</p> <p>5 -and-</p> <p>6 ROBERT M. SALLERBACH, ESQ., 7 Associate General Counsel 8 Becton Dickinson & Company</p> <p>9 -and-</p> <p>10 FREDERICK S. SAVAGE, ESQ., 11 Associate General Counsel 12 Office of the Vice President and General Counsel 13 Johns Hopkins University</p> <p>14 Counsel for Plaintiff Becton Dickinson 15 and Company</p> <p>16 CONWOLLY, BOVE, LODGE & BUTT 17 BY: GERARD M. O'ROURKE, ESQ. and 18 W. RICHARD FOWERS, ESQ.</p> <p>19 -and-</p> <p>20 LYON & LYON 21 BY: CON A. BLOOMBERG, ESQ., 22 JEROLD B. BRILLY, ESQ. and 23 RUSCH G. CHAPMAN, ESQ. (Los Angeles, California)</p> <p>24 Counsel for Defendant CellPro</p> <p>25 - - -</p>	<p>Page 2</p> <p>1 THE COURT: Actually, I was going to do</p> <p>2 the opposite.</p> <p>3 MR. WARE: You want to hear the whole thing?</p> <p>4 THE COURT: No. I thought I'd pick a couple</p> <p>5 just to talk about where we are with them.</p> <p>6 I know that the subject of the injunction is</p> <p>7 going to be the meat of any argument we have today.</p> <p>8 Let's see if we can clear some of the other</p> <p>9 issues up first.</p> <p>10 MR. WARE: All right.</p> <p>11 THE COURT: And then come back.</p> <p>12 But people won't leave today without getting</p> <p>13 a chance to walk through all of the issues on the</p> <p>14 injunction.</p> <p>15 But let's talk about -- I guess we've got</p> <p>16 the marking defense. We've got Beverly documents. We've</p> <p>17 got misuse.</p> <p>18 Why don't we talk about misuse for a minute?</p> <p>19 Who wants to talk about that defense and where it is?</p> <p>20 MR. BLOOMBERG: I'm happy to address that,</p> <p>21 your Honor.</p> <p>22 THE COURT: Good. Okay.</p> <p>23 MR. BLOOMBERG: As we indicated in our brief</p> <p>24 with respect to misuse, in order for judgment to be final,</p> <p>25 a claim must be fully adjudicated. And while the claims</p> <p>Page 4</p>
<p>Page 3</p> <p>1 PROCEEDINGS</p> <p>2</p> <p>3 (Proceedings commenced at 10:30 a.m.)</p> <p>4</p> <p>5</p> <p>6 THE COURT: Okay. We're ready to get</p> <p>7 started.</p> <p>8 MR. WARE: May I begin, your Honor?</p> <p>9 THE COURT: Sure.</p> <p>10 A few final papers slipped through last</p> <p>11 night that I have not yet read, but you should assume</p> <p>12 I've read everything.</p> <p>13 MR. WARE: We always do, your Honor.</p> <p>14 THE COURT: I remember walking past some of</p> <p>15 them last night.</p> <p>16 MR. WARE: We like to think in the middle of</p> <p>17 the night there's a reason why we're there.</p> <p>18 THE COURT: I thought what we'd do is a</p> <p>19 variation on pick a topic.</p> <p>20 MR. WARE: The suggestion that I had was that</p> <p>21 we begin generally the subject of the injunction, where</p> <p>22 there are, I think, the most issues to discuss, and that</p> <p>23 we perhaps address some of the issues separately and</p> <p>24 both sides be heard on them, and then move on to</p> <p>25 another point. There are a number of discrete issues.</p>	<p>Page 5</p> <p>1 of the patents here involved have been found to be valid</p> <p>2 and infringed, nevertheless, there's an issue as to</p> <p>3 whether or not those claims are unenforceable because of</p> <p>4 misuse.</p> <p>5 Under 35 United States Code 271, Subpart (d),</p> <p>6 Subpart (5), the statute sets out that misuse or an</p> <p>7 illegal extension of a patent right by reason of</p> <p>8 conditioning a license of rights to a patent on the</p> <p>9 acquisition of rights in another patent where the patent</p> <p>10 owner has market power in the relevant market is a</p> <p>11 defense.</p> <p>12 And that's the situation here. Almost a</p> <p>13 textbook example of misuse is contained in Defendant's</p> <p>14 Exhibit No. 709.</p> <p>15 Your Honor will recall that that is a letter</p> <p>16 dated April 15th, 1992 from Baxter, where they indicated</p> <p>17 that they were no longer interested in granting a</p> <p>18 license with a running royalty rate and a lump-sum</p> <p>19 payment, but wanted from CellPro exclusive rights to</p> <p>20 CellPro's patents in Europe and Japan and nonexclusive</p> <p>21 rights in North America.</p> <p>22 THE COURT: How do you propose to resolve</p> <p>23 this issue?</p> <p>24 MR. BLOOMBERG: I would propose that discovery</p> <p>25 be taken on the matter and that it be tried before a jury.</p>

1 THE COURT: Mr. Ware? I've read the briefing
2 on the topic.
3 MR. WARE: Well, we have not actually briefed
4 the substance of the topic. I think there was brief
5 comment on it in the injunction brief that we filed.
6 As far as where this is, the patent misuse
7 issue was, in fact, stayed by agreement of the parties,
8 and what we would propose to do, if CellPro is unwilling
9 to withdraw this defense, is we would propose to set a
10 briefing schedule and we will brief it. We think it can
11 very easily be disposed of as a matter of law.
12 THE COURT: You mean brief a summary
13 judgment?
14 MR. WARE: Yes. A summary judgment briefing
15 schedule.
16 THE COURT: The parties agree to defer the
17 presentation of the defense.
18 Was that in response to my comment that I
19 would otherwise shoot it into outer space, or what does
20 the agreement require?
21 MR. WARE: The original agreement was, I
22 think -- the original agreement was crafted at the very
23 beginning of the case, probably even before there had
24 been hearings before the Court. And at that time I
25 think that the thinking was probably on the part of

1 both parties that, to the extent that the parties can
2 avoid the unnecessary cost of antitrust-type discovery
3 and proceed with the patents, that they ought to do so.
4 Moreover, at least at that time, as I recall
5 it, the patent misuse defense was, in substance, a
6 hand-guards-type defense. And so, therefore, if the
7 patents were found to be valid, there would be nothing
8 left of the defense. And that's a further reason that
9 we contend now that there is no justification for going
10 forward with this defense in light of the Court's
11 findings.
12 But I think that what was contemplated at the
13 time, or at least as the stay was written, the entire
14 patent case was to be resolved and disposed of before
15 dealing with the patent misuse issue, since CellPro has
16 now raised an objection to entry of permanent -- entry
17 of a permanent injunction as part of a final judgment,
18 because technically its patent misuse is pending.
19 We would like to dispose of the patent misuse
20 defense so that there will be no question about the
21 Court's entry of final judgment, including a permanent
22 injunction.
23 THE COURT: All right.
24 MR. WARE: We certainly do not think it would
25 be appropriate to open up antitrust-like discovery on an

1 issue that we truly believe could not survive a Rule 11
2 motion.
3 THE COURT: Well, are you in a position -- I
4 mean, do you know what you're moving for summary judgment
5 on?
6 MR. WARE: Yes.
7 THE COURT: What the facts are that they'll
8 be relying on?
9 MR. WARE: Yes. I think that there are
10 several points here that need to be kept in mind.
11 In the first place, as I understand it, and
12 based upon what Mr. Bloomberg just said, in addition to
13 the hand-guards-type defense, which I assume Mr.
14 Bloomberg would agree, in light of the Court's rulings,
15 doesn't survive as a patent misuse defense, but, in
16 addition, this argument -- the patent-misuse argument
17 seems to be based entirely on an April 15th letter from
18 Baxter to CellPro, which the Court will recall from the
19 trial, in which Baxter simply made a proposal that the
20 license include distribution of CellPro's products in
21 Europe.
22 And the statement that Mr. Bloomberg just
23 made about conditioning anything on rights under CellPro
24 patents is nowhere contained in that letter and it has
25 never been suggested in five years of litigation until

1 this day that that had anything to do with it.
2 But, very briefly, we find no legal support
3 for the proposition that a licensee, such as Baxter,
4 cannot ask for distribution as part of a proposal for
5 the -- that is, distribution of the licensed product
6 itself, a product that an infringer could not sell in
7 the United States or could not export under any
8 circumstances.
9 Secondly, as the Court is aware, this
10 proposal never came to fruition and defenses such as
11 this do not come up when the other party rejects the
12 proposal. And the parties move on in their negotiation.
13 One does not go back and reconstruct
14 negotiations to find one proposal made on one day that
15 was not accepted and turn that into a patent misuse
16 defense. This is a proposal that never happened.
17 And, thirdly, as the Court is aware from
18 the trial, on July 15th, 1992, Baxter reiterated its
19 earlier offer of a pure patent license. That is, it
20 said, essentially, We thought you were interested in
21 talking to us about distribution, which is certainly
22 supported by the evidence in this case, but if you're
23 not interested in talking to us about distribution,
24 fine. You can have the license that we offered in the
25 first place.

1 And the law is absolutely clear that, even
 2 if there were misuse, that a purging of that misuse
 3 takes away the defense entirely.
 4 So what we're talking about is a three-month
 5 period in April that was -- certainly, if there was any
 6 misuse, was purged by July, when CellPro was given an
 7 opportunity on the same terms that were offered before
 8 to take a pure patent license. CellPro declined.
 9 There is no patent misuse under those
 10 circumstances, and that's a purely legal conclusion that
 11 the Court can draw based on undisputed facts.
 12 THE COURT: And what discovery would you want
 13 to take?
 14 MR. BLOOMBERG: We would want discovery with
 15 respect to the preparation of this April 15th letter. The
 16 authorship, the review of the letter, approval of the
 17 letter, comments with respect to the letter, documents
 18 regarding business plans or financial plans with respect
 19 to the countries affected by the conditioning of the
 20 license.
 21 As to the issue raised by Mr. Ware regarding
 22 this so-called purge letter, which I believe is
 23 Defendant's Trial Exhibit No. 637, I think the date is
 24 July 22nd, rather than July 15th, 1992.
 25 Your Honor will recall that there was a --

1 shortly thereafter, there was a meeting between Baxter
 2 and CellPro representatives, and Mr. Murdock has testified
 3 in court that at that meeting the terms of the so-called
 4 purge letter were not made available to CellPro, so we
 5 would want discovery with respect to that meeting as well.
 6 I think there would also --
 7 THE COURT: It sounds like what Mr. Ware is
 8 saying is it's almost a 12(b)(6) motion. And that is you
 9 can identify the letter and say that's the basis for your
 10 claim. But you can't identify any other facts that would
 11 show misuse that would be communications to your client.
 12 In other words, I know you want to go
 13 upstream from the letter, but how would that be relevant
 14 to establishing a claim if you can't show those matters
 15 were communicated to your client?
 16 MR. BLOOMBERG: I think there were actually
 17 two communications, your Honor. There was a meeting, I
 18 believe, in Southern California at a Baxter facility
 19 where the same representations were made orally, and then,
 20 as I understand it, from Mr. Murdock's testimony, the
 21 substance of that correspondence was confirmed in this
 22 letter.
 23 THE COURT: And so wouldn't discovery, at
 24 least in the first instance, go to what was communicated
 25 to CellPro and what was said in response to that?

1 MR. BLOOMBERG: Yes. To the extent Mr. Ware
 2 wants to raise an issue of this purge letter, it seems to
 3 me it would be appropriate to find out if those terms
 4 were really made available to CellPro. And as I say, Mr.
 5 Murdock's testimony is that when CellPro and Baxter met,
 6 they were not.
 7 THE COURT: And so when we talk about
 8 discovery, I had in mind discovery relating to those
 9 communications, as opposed to getting in and rolling
 10 around inside Baxter as to these matters. What
 11 additional discovery do you need with regard to those
 12 two communications?
 13 MR. BLOOMBERG: Beyond what I've already
 14 identified?
 15 THE COURT: Right.
 16 MR. BLOOMBERG: The only other issues that I
 17 think discovery would bear on this particular misuse would
 18 relate to the market power and the relevant market as
 19 conditions of 35 United States Code 271(d)(5).
 20 THE COURT: So have you deposed the people
 21 who -- the author of the letter, for example?
 22 MR. BLOOMBERG: We have taken his deposition.
 23 THE COURT: Have you deposed people that
 24 participated in the meetings?
 25 MR. BLOOMBERG: No, we have not.

1 MR. WARE: Your Honor, just a couple points.
 2 First of all, we would be prepared by the end
 3 of next week to file a summary judgment brief and it would
 4 be a proper summary judgment type issue that we would
 5 argue, and we would like the opportunity to do that
 6 rather than permit CellPro to start taking discovery on
 7 market power and everything else that you hear about in
 8 antitrust cases, which are very time-consuming and
 9 expensive.
 10 There is absolutely no law that exists that
 11 says someone making a proposal thereby engages in patent
 12 misuse.
 13 And I think we ought to have an opportunity to
 14 try to have this resolved as a legal matter before going
 15 into discovery.
 16 THE COURT: Okay. Let's pick another topic.
 17 Documents relating to Beverly.
 18 MR. BLOOMBERG: This issue, I think, your
 19 Honor, relates to dialogue between Dr. Beverly and the
 20 plaintiffs with respect to our inequitable-conduct claim.
 21 THE COURT: Okay.
 22 MR. BLOOMBERG: As I understand it, much of
 23 these documents have been asserted to be work product or
 24 attorney/client, and we don't think it's appropriate to
 25 make that claim in connection with a third party.

1 THE COURT: What's the matter in issue? What
2 is it that is still open that these documents are
3 relevant to?

4 MR. BLOOMBERG: Well, in view of your Honor's
5 ruling on inequitable conduct, I'm not certain that it
6 is -- that it remains a viable issue in the case. But
7 that was the purpose of our seeking those documents --

8 THE COURT: All right.

9 MR. BLOOMBERG: -- is they bore on
10 inequitable conduct.

11 THE COURT: All right. Let's move to the
12 topic of motion for -- let's move to the three issues
13 together. That is, the motion for injunction, the motion
14 for enhanced damages, and the application for an award
15 of fees.

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1 rather have them be reviewing a permanent injunction.
2 THE COURT: If I simply enter the order now
3 for the injunction, took the word "permanent" out, just
4 said order for injunction, partial stay of injunction,
5 that would be an appealable order?

6 MR. WARE: I believe so.

7 THE COURT: And the case would then go up,
8 presumably go up.

9 MR. WARE: Yes.

10 And under 1291(a), I think. And so I think
11 that -- I think it would be helpful to anybody reviewing
12 the record in this case to have the benefit of the
13 Court's further thoughts on some of the issues that
14 are before it now.

15 THE COURT: See, that's what I was wondering
16 about the relationship of the timing of the injunction
17 and whether or not plaintiffs would prefer to defer the
18 entry of the injunction until I have a chance to write
19 something on the subject of fees and enhanced damages.

20 And I take it that's what you are saying:
21 Is you would rather wait until I can get something
22 written on that?

23 MR. WARE: Yes. I think we're perhaps
24 being presumptuous, but we hope that could be in some
25 reasonable time frame. And I do think it would be

1 THE COURT (Continuing): If final judgment
2 is going to be deferred until I can deal with this
3 question of misuse, what happens to your application for
4 an injunction? Do you want a preliminary injunction?
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6 MR. WARE: I think that, since we're all here,
7 we'd like to argue it, but I think we would like a
8 permanent injunction. And I think it makes more sense,
9 because I think the patent misuse issue can be disposed
10 of quickly. And I don't see what the advantage is,
11 particularly given the stay we've proposed.

12 There is nothing that can't be addressed in
13 permanent injunction. Insofar as we have proposed that
14 any stay be conditioned on certain payments from
15 CellPro, we've asked that those payments be made based
16 on sales retroactively to March 12 anyway.

17 So I don't think a brief delay in entering
18 the injunction will affect that. And we have generally
19 accepted the proposition of a stay on the terms proposed,
20 such that, again, I don't think a matter of a couple of
21 weeks or so or a few weeks is going to make much
22 difference.

23 And I think that we would rather have the --
24 if this is going to go to the Federal Circuit, we'd

1 helpful to the Court of Appeals to have the benefit of
2 the Court's written decision.

3 THE COURT: All right.

4 MR. WARE: There's a sort of a procedural
5 piece of the attorneys' fee application that we might
6 just discuss briefly --

7 THE COURT: Sure.

8 MR. WARE: -- because, as we're going
9 through some of these items, to get them out of the way.

10 I think the issues are pretty
11 straightforward, as far as the Court's authority to
12 award fees. And I think that the issue that we seek
13 some guidance from the Court on has to do with the
14 submissions that the Court wants to see, in terms of
15 the backup information. We have provided to the Court
16 in the application a detailed breakdown by lawyer, by
17 time period of hours. And we have provided the billing
18 rates.

19 We have not at this time submitted to the
20 Court detailed, daily time reports of lawyers, and we
21 have not submitted to the Court at this time actual hard
22 copies of individual invoices for transcripts and things
23 like that.

24 We have provided the Court a -- subtotals
25 based upon an itemization of the types of different

1 costs that we're seeking. There's no indication in
2 the papers submitted by CellPro that there is objection
3 in concept to the particular types of expenses that we
4 are seeking. And as to the time detail, we have a couple
5 of concerns.

6 We have the concern that the time detail
7 itself contains information that we regard as
8 confidential work product, and we're reluctant to
9 provide it to opposing counsel, although we are not in
10 the least reluctant to provide it to the Court in
11 camera.

12 We also had requested some time ago from
13 CellPro the equivalent information from Lyon & Lyon,
14 and that was refused. It seems to us that if Lyon --
15 if CellPro is proposing to object specifically to the
16 number of hours spent in a time period or whatever,
17 that we would be entitled to see the time spent by
18 their lawyers as well, that that would be at least a
19 relevant piece of evidence.

20 It seems to us that CellPro -- from reading
21 the opposition brief, that CellPro's objection really is
22 not -- does not have anything to do with the time spent
23 on the case. The only substantive objection was the
24 suggestion that the billing rates ought to be
25 Wilmington billing rates, rather than national billing

1 rates.

2 CellPro has refused our request that they
3 provide information concerning Lyon and Lyon's billing
4 rates. We think that the billing rates are very much
5 in line with national firms engaged in the sort of
6 practice. But we're a little bit unsure as to what to
7 do at this point. We want to give the Court whatever
8 information it feels it needs to be able to make -- to
9 review the request.

10 And if that sort of detailed daily report is
11 something that the Court wants to go through over a
12 period of five years, again, we are happy to do it. But
13 we do have this concern about disclosure of all of the
14 details of every potential witness we ever talked to or
15 every issue we looked into or what-have-you.

16 And there was really a parallel situation
17 earlier in this case, when we sought discovery from
18 Lyon & Lyon with respect to the willfulness issue. And
19 we were not permitted to see any of their internal
20 records, really for the same reason. They were
21 concerned about work product.

22 And so it seems to us that, in light of that,
23 and in light of CellPro's refusal to provide the
24 information with respect to Lyon and Lyon's time, and in
25 view of the fact also that the fees, we think, that we're

1 requesting are considerably -- they're considerably less
2 than what the plaintiffs actually paid, they are, we
3 believe, considerably less than what CellPro paid to its
4 lawyers, that we really just should not have to make that
5 information available to CellPro.

6 But that's why we seek guidance.

7 THE COURT: Do you want to say something?

8 MR. BLOOMBERG: Well, I think that in order
9 for us to properly evaluate their application, we need to
10 see the supporting documentation, which we have not seen.

11 As to Mr. Ware's comments regarding our
12 billings, our understanding is that the standard is the
13 local fee rates, as opposed to rates in California.

14 As to Mr. Ware's comments that, as to the
15 willfulness, we were able to prevent plaintiffs from
16 taking discovery based upon attorney/client and work
17 product.

18 Your Honor will recall that much of our
19 documentation that was clearly work product or
20 attorney/client was found to be waived and made
21 available to the plaintiffs.

22 THE COURT: I have a couple thoughts.

23 My understanding is that at the moment, with
24 the application for fees pending -- and, actually, with
25 my invitation to plaintiffs to file the application,

1 that it's on my plate to resolve before the case goes
2 up.

3 I'd sort of prefer to find a procedural way
4 to send the case up and do a final review of this issue
5 if and when it comes back affirmed. But if I cannot do
6 that, I cannot do that.

7 There are a couple of advantages to doing it
8 that way. One advantage to doing it that way is that at
9 that point I think people -- we could have more of an
10 open review of the issue of fees and time put in and
11 comparison, and we could do it in the context -- I don't
12 know whether the Federal Circuit has a separate provision
13 for an award of fees or whether they remand it to the
14 District Court to take care of that issue, but the costs
15 and fees on appeal can then be added in with less concern.
16 And I can even refer to a Master or somebody like that to
17 review it.

18 If I cannot -- if I cannot put it off, and
19 if plaintiffs don't want me to put it off until the case
20 goes up, then what I'm inclined to do is the following:
21 I can tell you right now I'll apply a national standard
22 to the award for the calculation of fees and costs, as
23 opposed to a local Delaware standard, in part because I
24 don't want to restrain the national Bar with the high
25 Delaware rates that are billed.

1 Second, what I will do is the following:
 2 I'll take the information that the plaintiffs have given
 3 me as their best shot. I will review it, to see whether
 4 I think it is adequate. If I have any particular
 5 questions, I will let people know promptly in time to
 6 get information back to me.
 7 CellPro can review what it is that the
 8 plaintiffs have submitted and raise specific questions,
 9 if they want to, by category, by topic.
 10 But if there is a specific review, I am going
 11 to need to look at what is reasonable. And one way of
 12 looking at what's reasonable is looking at what CellPro
 13 did, in terms of their defense. That is, it was
 14 unreasonable to spend eight hours to prepare for that
 15 deposition. I'll look and see what the records of
 16 Lyon & Lyon show.
 17 So it's going to have to be an issue where,
 18 if there's a challenge to the fees, it needs to be
 19 identified, either by CellPro or by me in my review.
 20 And I know that there are lots of categories
 21 of areas where there's reasonable arguments that this
 22 shouldn't be included, this should be included. And I
 23 am open to hear argument on it. But if it's going to
 24 get into the files, I will find a way to get into the
 25 files to get it satisfied or find a way to articulate to

1 the Appeals Court, to the extent that I award fees, what
 2 I did and why I did it.
 3 MR. WARE: Would there be any merit to the
 4 idea of addressing, or making a determination about
 5 whether fees are to be awarded and under what statutes
 6 without actually calculating them and having it go up
 7 that way?
 8 THE COURT: That's why God invented lawyers.
 9 Judges don't know the answer to anything. They just
 10 pick what you say, until Exxon came along, and then I
 11 had to come up with my own independent view. I would
 12 have thought there are mechanisms to do that. That is,
 13 I intend to award.
 14 On the other hand, if, was the Appeals Court,
 15 I might say, Look -- well, if you go look at the world
 16 about what happens with fee applications, my general
 17 sense is that what happens is the case gets tried.
 18 Party makes an application for fees. The Trial Court
 19 puts it in its pocket. It goes up on appeal. It gets
 20 affirmed. If it gets affirmed, it comes back and the
 21 Trial Court resolves all of the issues about fees. Our
 22 local rule has a specific provision about the time
 23 period for filing fee applications, and I thought it
 24 was within a certain number of days after the decision
 25 came down from the Appeals Court. But why don't you

1 look at it and see?
 2 MR. WARE: Why don't we look at it and why
 3 don't we perhaps communicate back to the Court based on
 4 the comments the Court has made what we think makes
 5 sense to do at this point.
 6 THE COURT: When you look, you'll find a
 7 wonderful opinion by the Third Circuit on the types of
 8 attorneys' fees in civil rights cases that says that
 9 when you have a civil rights case, and you settle it, and
 10 the defendant gives to the -- gets from the plaintiff a
 11 general release of all claims, including claims relating
 12 to attorneys' fees, that's not a waiver of attorneys'
 13 fees under the Civil Rights Law.
 14 MR. WARE: I think I remember that case.
 15 THE COURT: I don't think many people in the
 16 Bar know that, but the plaintiffs' bar likes to get a
 17 case, get all the money they can, settle, say they waive
 18 our claim for fees and then fees for fees under the
 19 Civil Rights Law.
 20 Not many Circuit Judges write opinions that
 21 bury those type of problems in the law, but we had a few
 22 in the Third Circuit that did for a while.
 23 In any event, look at it. See what you want
 24 to do. I'm going to leave the bench today and assume
 25 that I have on my plate the subject of an application

1 for fees and costs and the subject of enhanced damages
 2 and I'll begin working on it. I'll be applying the
 3 standards that I would otherwise apply to it.
 4 To the extent that CellPro raises damages
 5 with regard -- awarding fees for appropriateness of
 6 certain matters, I looked at the briefing. I didn't
 7 notice in the briefing there were many issues that I
 8 thought raised particular factual problems, but I'll
 9 look. And if CellPro wants to go back and look at it
 10 again, that's fine with me. I am interested in getting
 11 the right result here.
 12 But I have in the past, and frequently,
 13 when a party objects to a rate, I say, fine. So tell
 14 me your rate. Then I have some indication of
 15 reasonable -- all right. So that's where we are on
 16 that.
 17 And I raise all that in part because I
 18 thought, one, and I'm sure plaintiffs have thought
 19 about this, one way to go would be to simply enter
 20 the injunction, and let people go up to the Federal
 21 Circuit in the context of a decision that basically
 22 says, this implements the jury's decision.
 23 We've got some other issues to take care of
 24 here, but there's no reason to delay the case going up.
 25 But if the plaintiffs want me to write out on the issue

1 of enhanced damages and the award of attorneys' fees,
2 I'll do that, too. I will assume, unless you apply
3 otherwise --

4 MR. WARE: That's our present thinking.
5 Yes.

6 THE COURT: Okay.
7 On the subject of the terms of the proposed
8 permanent injunction, I have read the briefing. I
9 think I understand the positions of the parties. I
10 think they are pretty clear. I am happy to hear
11 argument, if people want to supplement what they've
12 already said in the briefing. But I don't know that
13 I had any particular questions. I've just got some
14 reading to do, to solve certain questions I've got.

15 MR. WARE: Let me just ponder that for a
16 minute.

17 (Pause while Mr. Ware and Mr. Ellis
18 conferred.)

19 MR. WARE: What we are thinking about, your
20 Honor, would be just highlighting a few of the issues
21 that are maybe most highly contested, and making sure
22 that we have anticipated any questions that the Court
23 might have, and certainly responding to anything further
24 that CellPro has to say on the point.

25 MR. BLOOMBERG: With your Honor's permission,

1 Mr. Riley would argue the injunction on behalf of CellPro.

2 THE COURT: Fine.

3 MR. REILLY: If I may stay here until he's
4 finished, your Honor. I might want to take notes.

5 THE COURT: Whatever you want.

6 MR. WARE: Okay. As the Court is aware,
7 the injunction is structured to include essentially four
8 elements, one being a prohibitory injunction, one being
9 a mandatory injunction, the third being a temporary stay,
10 and the fourth, which I guess is part of the temporary
11 stay, relates to calculation of payments of incremental
12 profit during the stay.

13 I don't think I need to say very much about
14 the prohibitory injunction, other than to emphasize that
15 it is key we believe that there be one. That the end
16 point must be an injunction here. And, in the absence
17 of an injunction, the value of patent rights would be
18 very greatly diminished and would become very difficult
19 for inventors and non-profit institutions, such as Johns
20 Hopkins University, to be able to license out their
21 patents. And there certainly is no exception for
22 infringement that happens to involve medical products.
23 There are injunctions entered all the time against
24 infringing medical devices.

25 The other aspect of the prohibitory

1 injunction that I might comment on briefly is the
2 proposed two-year injunction with respect to sales in
3 Europe. And there, of course, is a stay of that. But
4 I think that the emphasis really is on a couple of
5 points. One is that this is a remedy for infringement
6 in the United States, and it is really not very different
7 from the very typical sort of trade secret injunction,
8 which typically are worldwide, when somebody has
9 misappropriated a trade secret, and thereby acquired for
10 themselves a head start in a market. And their having
11 done so is very destructive of the marketplace for the
12 licensed patent -- for the patent-holder or the
13 licensee.

14 And so it is very common to enter that sort
15 of injunction. That's what that's about.

16 In terms of the mandatory injunction, the
17 repatriation of the 12.8 hybridoma we think is vital.

18 We have addressed in the papers the
19 conclusion that CellPro clearly did infringe in the
20 United States through its ongoing use of the 12.8
21 hybridoma after the issuance of the patent.

22 This is a situation where, by CellPro's
23 attempt to evade the United States patent laws by
24 sending hybridoma cells to Canada in the midst of
25 litigation, the patent-holders have been deprived of

1 rights that they would otherwise have had.

2 They would have had the right, upon a finding
3 of infringement, to request destruction of the
4 infringing hybridoma, in which case it could not have
5 been sent to Canada.

6 They could have requested, and the Court
7 would properly have entered an injunction against
8 exporting the infringing hybridoma.

9 So they were deprived of those rights. And
10 to remedy that, the Court must require them to bring it
11 back to the United States.

12 It's really no different than a party that
13 sends out or smuggles out of the United States stolen
14 goods. They are still within the possession and
15 control -- not possession, but control of the infringer,
16 and they ought to be brought back.

17 We even know, by reason of the filings that
18 have been made most recently, that CellPro itself
19 recognized that the operation in Canada was really a
20 sham and that, as soon as the jury verdict came down in
21 the first trial, CellPro ceased manufacturing abroad.
22 They had no real intention of manufacturing there.

23 The mandatory injunction also includes a
24 destruction order. I think, ultimately, the plaintiffs
25 are entitled to it.

1 The plaintiffs should not be in a position
2 where they have to police all of the activities of
3 CellPro regarding 12.8. It is very easy to clone
4 hybridoma cells and ship them out of the United States.
5 We shouldn't have to be guarding that. We shouldn't have
6 to learn that at some point in the future that, all of a
7 sudden, people are being supplied with 12.8 antibody from
8 the Cayman Islands or somewhere else.

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2 MR. WARE (Continuing): And so we think that
3 that's an appropriate order ultimately.
4 However, in view of the stay that we seek,
5 that will not come to pass in the near term.
6 What I might suggest, because I think there
7 are enough differences here that -- I might suggest that
8 we hear from Mr. Reilly on those aspects of the
9 injunction before turning to the stay, because otherwise,
10 I will have kind of a long presentation here.

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2 THE COURT: What's the evidentiary record on
3 the shipping of the 12.8 hybridoma to Canada?

4 MR. WARE: There had been summary judgment
5 briefing in 1985 on the issue, and there was deposition
6 testimony of a Mr. Bordinaro from CellPro that had been
7 submitted to the Court at the time and Mr. Bordinaro,
8 in fact, submitted a declaration.

9 There are certain facts that are undisputed,
10 including the fact that it was in 1993 that CellPro
11 shipped the hybridoma to Canada. And the various facts
12 on which we -- the various facts we have pointed to in
13 terms of CellPro's maintenance and use of the 12.8
14 antibody in the United States after the patent issued
15 and before the cells were shipped to Canada are also
16 undisputed. That is, they come out of Mr. Bordinaro's
17 deposition.

18 So that's really the basis of the
19 evidentiary record, then.

20 Mr. Bordinaro acknowledged that the -- that
21 although CellPro first cloned the cells that they
22 obtained from the Fred Hutchinson Cancer Research
23 Institute in -- I believe it's early 1990, that the
24 cell bank that they made out of those cells was not
25 even released for use until -- I believe it was in '91

1 or '92. Maybe even in '93, but sometime after the
2 patent issued, because there's a whole series of steps
3 of quality-control testing and things that have to be
4 done before you can release it.

5 But, again, it's based on the evidence --
6 that -- both documentary and deposition testimony of
7 Mr. Bordinaro.

8 THE COURT: All right.

9 MR. REILLY: Good morning, your Honor.

10 THE COURT: Good morning.

11 MR. REILLY: Let me start with the
12 injunctions, request for repatriation of hybridoma in
13 Canada. This was summary judgment briefed in 1995. I
14 think what happened is the trial crept up on us and it
15 was never argued. It's briefed a lot more thoroughly in
16 1995. I would refer the Court to DI-158, 159, 249 and
17 269 was the briefing on that.

18 We have a rather different interpretation of
19 Mr. Bordinaro's testimony. The facts, as I understand
20 them, is that -- and this much is certainly undisputed --
21 the 12.8 antibody was discovered before the '204 patent
22 issued.

23 There were six vials shipped to Canada.
24 The six vials shipped to Canada were frozen. They
25 remained in a frozen state, unaltered and undealt

1 with, except to keep them cold so they would not die,
2 until a time in 1993, when they were sent to Canada.

3 Simply put, CellPro's position is that the
4 hybridoma is not an infringing product because, even if
5 it is within the claims of the patent, the patent
6 didn't issue until subsequently.

7 It's sort of like the parable of the
8 widgets, if I may say, your Honor. If you make a
9 bushel basket full of widgets and you have them there
10 and then one subsequent day I get a patents issued to
11 me that reads on the widgets, they do not become
12 infringing widgets. We know that because Section 271(a)
13 tells us that. He who makes, uses or sells during the --
14 in the United States during the term of the patent
15 infringes and not otherwise.

16 So a device or a product that is made before
17 a patent issued does not become an infringing product if
18 the patent issues.

19 If you thereafter use it or sell it, those
20 are acts of infringements.

21 But, certainly, you would be perfectly
22 within your legal rights to store your widgets for 17
23 years or until I fail to pay my maintenance fee or
24 something or my patent is declared invalid.

25 Simply storing a product that was made

1 before a patent issued does not turn that product into
2 something that infringes. The mere act of keeping it
3 around, and the mere act of shipping it out of the
4 country, are not acts of infringement. And we do cite
5 law on that.

6 If you didn't want to keep your widgets in
7 the United States for 17 years until my patent expired,
8 you could ship them to Canada. And if I had no patent
9 rights in Canada, you could just sell them in Canada,
10 and that would not be an act of infringement.

11 And, again, what tells us that is 271(a),
12 which says that he who, within the term of the patent
13 in the United States, makes, uses or sells, infringes
14 the patent.

15 The case that plaintiffs have cited for the
16 point that mere storage constitutes an infringing act is
17 what I call the howitzer case. It's the Olson case.
18 Very strange case. And I think it's sui generis. It
19 dealt with howitzers. And the Court says the use of
20 howitzers in peacetime is to just sit around and be a
21 deterrent, so their storage is use.

22 The other distinguishing fact about that
23 case is the howitzers were made during the term of the
24 patent. The 12.8 antibody was discovered before the
25 patent issued. So the mere fact of shipping the

1 hybridoma to Canada, the mere fact of storing it in its
2 frozen state before it went to Canada cannot be acts of
3 infringement.

4 There's no act of infringement that has been
5 committed with respect to those six frozen vials in
6 Canada. They were thawed out after and used in Canada,
7 but not in the United States. It's simply our position
8 there has been no act of infringement with respect to
9 those vials. Plaintiffs have called this an evasion of
10 the U.S. patent laws, but it's no more of an evasion
11 than if I moved to Switzerland and lawfully pay my taxes
12 in Switzerland. Once I move out of the country and
13 don't have any activities here that tax is due on, it's
14 certainly not an evasion of the U.S. tax laws.

15 So I think plaintiffs' position just
16 basically violates the principle of territoriality of
17 the patent laws and there's no basis to repatriate that
18 hybridoma.

19 The other thing I should mention is that
20 CellPro does not really own it free and clear. The
21 hybridoma is licensed from the Fred Hutchinson Cancer
22 Center and there's provision in the license agreement
23 that if the -- the license ever terminates, CellPro
24 would have to return any of the remaining stock of
25 the hybridoma to the Fred Hutchinson Cancer Center.

1 The other point I would make, your Honor,
2 is that to actually round up the hybridoma and kill it
3 would be as one clinician said to me when I mentioned
4 this, it would be like killing Einstein.

5 This is not the situation where someone
6 makes a bunch of Rolex watch knock-offs and they call a
7 press conference and hire a steam roller and flatten
8 the watches.

9 A hybridoma, as your Honor well knows, is
10 a unique, living organism. You can never get another
11 one like it as a practical matter. And if it were
12 ordered destroyed then, as a practical matter, neither
13 CellPro nor anyone else could begin using it again when
14 the patent expires or is ultimately found invalid or for
15 any other reason becomes unenforceable.

16 Something made before a patent begins, there
17 ought to at least be a right to store it until the patent
18 term is over. And I think that the law should be clear
19 on that, and that to actually order this hybridoma
20 destroyed really would be a great loss to science and
21 way, way beyond the bounds of, I think, anything that
22 the Court should fairly do, even if there were an act
23 of infringement here, which there hasn't been.

24 THE COURT: During the discovery, was there
25 discovery of documents about the motive that CellPro had

1 and communications that related to the decision to ship
2 the hybridoma to Canada?

3 MR. WARE: Well, there was discovery of
4 communications from Lyon & Lyon to CellPro. This was a
5 scheme that was devised by CellPro and its lawyers, and
6 CellPro --

7 THE COURT: Were these documents withheld as
8 privileged?

9 MR. WARE: They were produced.

10 THE COURT: They were produced?

11 MR. WARE: Yes.

12 THE COURT: And they are in the summary
13 judgment briefing?

14 MR. WARE: I don't think so. I don't think
15 so.

16 I don't know -- well, no, I don't think so.

17 THE COURT: Can you provide them?

18 MR. WARE: Yes. We can provide them.

19 THE COURT: To the extent there are documents
20 that may shed some lights on CellPro's intent at the
21 time, I'd be interested in seeing them.

22 MR. WARE: Yes. Now, there was no
23 discovery, that is whether we deposed Mr. Bloomberg,
24 for example, I don't think we went into those. But
25 those documents themselves do exist.

1 cited in our reply brief. It's called Amgen versus
2 Ellenex (phonetic) that actually does involve frozen
3 cell lines, oddly enough, in Bothel (phonetic),
4 Washington, a different company. The decision was
5 written by Judge Dimmick, who was the original Judge
6 in the declaratory action brought in Washington.

7 And so one thing we do know if this case had
8 not left Washington and if that's where it was in 1993,
9 that Judge Dimmick's view would have been that the very
10 maintenance of the cell line that is described by
11 CellPro is, in fact, an infringing use.

12 And so, had we stayed in Washington, I'm
13 sure that Judge Dimmick would have been quite prepared
14 to enjoin the shipment of those cells out of the
15 Washington.

16 What is also different about this is that
17 the notion that's presented here is that these are just
18 a bunch of different vials, and that the particular vial
19 that they sent to Canada itself wasn't thawed and tested.

20 But a hybridoma is a hybridoma. And that's
21 how a hybridoma is stored. It's stored in a bunch of
22 vials. And so you cannot simply say that every time you
23 pull one off, that you are -- that that had nothing to
24 do with the 12.8 hybridoma.

25 When you do quality-control testing of the

1 I do want to emphasize that, as Mr. Reilly
2 said, CellPro is a licensee from the Fred Hutchinson.
3 Nobody is talking about destroying the Fred Hutchinson's
4 12.8 hybridoma. These are simply cells that were cloned
5 off of the hybridoma at Fred Hutchinson.

6 And our point is simply that CellPro should
7 not be permitted to continue to be in possession of
8 hybridoma cells, because it is just very easy to ship
9 them out of the country.

10 So -- but we are not talking about killing
11 some living thing that can never be reproduced, because
12 that's exactly the point of all of the cells in the
13 freezer at Fred Hutchinson. You can simply clone more
14 off of them.

15 I think also that what Mr. Riley is missing
16 in his discussion of widgets is that these aren't
17 widgets, and what you do with a hybridoma is you store
18 it and you test it from time to time so as to be able
19 to replenish your stock.

20 And so that is the use. Putting hybridoma
21 into service is basically putting it into the freezer
22 and pulling cells out from time to time and doing
23 quality-control testing. So it's a very different
24 situation from widgets.

25 And there's an interesting case that is

1 hybridoma, you're testing cells in a particular vial,
2 because the results of that test tell you something
3 about all of the cells. And so you can't just say
4 there are billions of cells, and so we only tested
5 these cells and we sent these cells. I mean, the
6 patent covers a hybridoma, and that's what a hybridoma
7 is. It's a whole lot of cells that have been cloned
8 that are all identical that are sitting in the freezer
9 in vials. So...

10 MR. REILLY: Your Honor, the patent -- what
11 right is secured by a patent is what we need to focus
12 on. The patent doesn't really cover a hybridoma. The
13 patent covers the right to exclude others from making,
14 using and selling the hybridoma in the United States
15 during the term of the patent. That is exactly what
16 the patent covers, or is what it has been ruled to cover
17 by the Court.

18 And, again, the fact that this hybridoma was
19 made before the patent issued and that the particular
20 six vials that were shipped to Canada just remained in
21 the frozen state since before the patent issued until
22 1993, when they were shipped up to Canada, they simply
23 were not used in the United States.

24 As for your Honor's question about what
25 CellPro's motive is in shipping them to Canada, I would

1 first suggest to your Honor that that is irrelevant.
 2 The only thing relevant is that Canada is not the
 3 United States and 271(a) says that you've got to be in
 4 the United States to infringe.
 5 Beyond that, your Honor, there is --
 6 THE COURT: It sounds like a good business
 7 opportunity, if somebody could rent a hospital ship and
 8 become some kind of a freezer bank, stay off the coast.
 9 We hold it while you litigate?
 10 MR. WARE: We hold, you litigate.
 11 MR. REILLY: They don't have to hold it.
 12 They can use it to their heart's content in any country
 13 but the United States is my point.
 14 THE COURT: A lot of Caribbean countries.
 15 It's too hot down there. That's why you picked Canada.
 16 MR. REILLY: There is some evidence that we
 17 recently submitted on CellPro's intent.
 18 On the question of -- of intent, we did
 19 submit a declaration of Dr. Tarnowski (phonetic) with
 20 CellPro, who reports that the hybridoma, after it got
 21 to Canada, was thawed out and was used to make
 22 biotinylated 12.8 antibody, which was not sold into the
 23 U.S., I believe, but it was sold in Europe.
 24 So the biotinylated 12.8 was made from the
 25 hybridoma in Canada for sale in Europe which, again,

1 is lawful, given the territorial scope of the United
 2 States patent.
 3 The next point that Mr. Ware --
 4 THE COURT: You could call that ship
 5 Patent Pending.
 6 MR. REILLY: You could.
 7 THE COURT: Go ahead. I'm sorry.
 8 MR. REILLY: The next point that Mr. Ware
 9 raised, your Honor, was about the two-year prohibitory
 10 injunction in Europe.
 11 As we read that proposal, it would forbid
 12 CellPro from making any stem cell antibody product in
 13 Europe, even if the antibody was 12.8 that had never
 14 even been in the United States during the term of the
 15 patent, or even if it had been some other antibody.
 16 And the idea is a head-start injunction.
 17 I think it's -- let me get to my notes for
 18 a moment.
 19 (Pause.)
 20 MR. REILLY: I think it's telling, your
 21 Honor, that there are no patent cases that are cited in
 22 support of this notion that you can have a head-start
 23 injunction as a remedy for past patent infringement.
 24 The remedy for past patent infringement is
 25 the remedy that the plaintiffs have already had in

1 this case. They have had a jury award them damages
 2 based on their sales in Europe.
 3 The section of the patent statute that deals
 4 with injunctions speaks of the injunction as being a
 5 remedy to prevent infringement.
 6 Selling a stem cell antibody, making a stem
 7 cell antibody product in Europe, where the plaintiffs have
 8 no patent coverage and concede that they can't now get
 9 any, is not an infringement of the U.S. patent law.
 10 And if the court were to enter an injunction
 11 granting that relief, the Court would really be giving
 12 them a remedy that they have already had a damages remedy
 13 for. The whole idea of a reasonable royalty damage claim
 14 is to compensate the plaintiffs for past sales.
 15 We are now talking really about future
 16 conduct. And I think that the -- the injunction can't
 17 really enjoin something that's not an act of infringement.
 18 And to take an antibody that is wholly
 19 developed in Europe, or to taken 12.8 antibody that has
 20 never been in the United States during the term of this
 21 patent, simply would not be an infringement of the U.S.
 22 patent laws.
 23 The other point on that, your Honor -- and
 24 we've briefed this -- is the whole question of
 25 international comity and the extraterritorial effects

1 of patent laws, we have a declaration we filed from Mr.
 2 Colin Overbury, who is a high official of the European
 3 Commission, that talks about the effect that
 4 extraterritorial enforcement of U.S. patent laws would
 5 have on the important antitrust and competition policies
 6 of the European union. And he opines that this is
 7 something that would implicate the comity issues and it
 8 could provoke international retaliation.
 9 The other thing I would say, to go on about
 10 these trade secret cases, is that they really, really
 11 are distinguishable, when you consider the difference
 12 between what a trade secret is and what a patent is.
 13 Trade secrets are creatures of state law.
 14 The cases are cases the plaintiff cites, where the Court
 15 is sitting in diversity and applying state law. Trade
 16 secrets aren't necessarily territorial in scope. You
 17 can come in and steal somebody's trade secret and you're
 18 still a thief. If you come into the United States and
 19 see somebody's patented device in operation, you are
 20 free to take it with you and use it anywhere where he
 21 does not have patent coverage.
 22 I would say, too, that the -- there's an
 23 international network of cooperating patent laws that
 24 really finds no counterpart in trade secret law.
 25 Trade secret law is basically a state common-law thing

1 that recently has been -- relatively recently has been
2 codified in some states.

3 Whereas you look in the patent laws, and the
4 U.S. patent laws are carefully tailored to intermesh
5 with international patent laws. There are -- wherein
6 all countries respect the territoriality of each
7 other's patent laws and expect that they will not
8 apply extraterritorially.

9 And to render -- issue an injunction in a
10 patent case that has extraterritorial effects that
11 would say to CellPro, Even though your activities in
12 Europe do not infringe any U.S. patent and can't,
13 because they're beyond the territorial scope of that
14 patent, still we are enjoining you for patent law
15 reasons.

16 That would be an extraterritorial
17 enforcement in a situation where you've got a rather
18 complex international scheme of rights, all countries --
19 each country understands that its own patent laws are
20 territorial. And the way the European union would be
21 if these plaintiffs wanted patent protection in Europe
22 to prevent their business competitors from selling a
23 stem cell antibody product in Europe, they should have
24 gotten patent production here.

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2 MR. REILLY (Continuing): They did not fill
3 the requirement to get patent protection in Europe, so
4 they have not got it. So free competition is what
5 should obtain.

6 Trade secrets are worldwide. And trade secret
7 is a potentially -- I should not say infinite, but
8 indefinite duration. As long as it remains a secret, it
9 is entitled to trade secret protection.

10 By the same token, if you reverse-engineer a
11 trade secret -- if you make something that tastes just
12 like Coca-Cola without cracking the safe and getting the
13 Coca-Cola formula, then you are perfectly legal to do
14 that.

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2 MR. REILLY (Continuing): So there are
3 extremely large and significant differences between
4 the nature and scope of the right that patent confers
5 and the right that trade secret protection confers.

6 The right that trade secret protection
7 confers is simply a right to prevent people from, you
8 know, invading your secret and igniting it. The right
9 that patents confers is a right to exclude others for
10 a limited term in a limited place that in this case does
11 not include Europe.

12 So, for all these reasons, we think that
13 the trade secret cases are totally inapt. There's a
14 good reason why they cite trade secret cases and not
15 patent cases. And there are serious issues of
16 international comity that would be implicated if that
17 kind of an injunction were issued.

18 MR. WARE: I think I have about three or
19 four very quick comments.

20 First, on the trade secret cases, it's
21 actually interesting. Trade secret law is a creature
22 of state -- of the states, not federal, and those trade
23 secrets are, in many cases, not even recognized in many
24 foreign countries, and yet certainly courts in the
25 United States feel perfectly able to enter orders like

1 this and would certainly similarly feel comfortable
2 entering an order against a United States company that
3 steals trade secrets in the United States and ships
4 products out, or ships confidential work papers or
5 scientific technical papers out.

6 They could be ordered to bring them back
7 even if they had shipped them to -- I was going to say
8 China, which maybe does not recognize them, or even if
9 they've got them on that offshore tender someplace.

10 THE COURT: Even if they take them to Spain
11 and Germany and they used to work for Ford Motor
12 Company.

13 MR. WARE: These things do happen from time
14 to time.

15 And the United States courts do exercise
16 their authority to provide remedies that are meaningful
17 remedies for past violations.

18 And the Federal Circuit has made clear on
19 a number of occasions that it is perfectly within the
20 authority of a District Court to enter injunctions that
21 not only prevent future infringement, but that remedy
22 past infringement, that will have an impact in the
23 future if not remedied.

24 And that's what's going on here. There have
25 been injunctions entered even in medical cases where an

1 infringer has been ordered to destroy clinical data that
2 was generated through infringement. That's the Pfizer
3 case. And the data itself is not infringing, but it's
4 a remedy that was granted.

5 And we are not asking for that particular
6 remedy, but we are asking for remedy for conduct in the
7 United States that unfairly impacts the future
8 development of Baxter's business in Europe as a result
9 of the head start.

10 So I guess I'd move on now to the stay of
11 the injunction.

12 MR. REILLY: If I may just respond to that
13 very briefly, your Honor...

14 THE COURT: Yes.

15 MR. REILLY: Again, for past infringement,
16 they've already had their remedy. They've now gotten
17 the verdict for damages on a reasonable royalty theory.

18 The other point to keep in mind about this
19 head start injunction in Europe is that the logic of
20 such an injunction I think has not really been
21 supported in the proof. Plaintiffs assert in their
22 briefs that, but for infringement in the United
23 States, we would never have gotten going in Europe.

24 It's nowhere been proved on this record
25 that that is true. And, in fact, Dr. Tarnowski's

1 they are doing the manufacturing in the United States,
2 in Bothel, Washington, and that what we're actually
3 talking about is an injunction that will have -- will,
4 in the end, amount only to enjoining them from
5 exporting goods from the United States.

6 There's no evidence that they have any
7 other plans anyway. So in terms of the impact of this
8 injunction, it may be only United States activities
9 anyway.

10 MR. REILLY: Well, your Honor, I would
11 invite Mr. Ware to withdraw that part of his proposal
12 that would call for an injunction in Europe. That's why
13 we have this issue.

14 MR. WARE: But if you are manufacturing in
15 the United States, you can't even raise this point.

16 MR. REILLY: All right. I think my problem,
17 your Honor, is that the injunction, the proposed
18 injunction, as written, would forbid CellPro for two
19 years from making any stem cell antibody product in
20 Europe, regardless of where they got the antibody. And
21 if they didn't get it in the United States during the
22 term of the patent, it simply does not infringe.

23 And what CellPro may do later, I mean,
24 certainly, it is a business option for any company that
25 is blocked under U.S. patent law to manufacture where

1 recently-filed declaration demonstrates that CellPro
2 could have, and did, for a while, manufacture the
3 biotinylated antibody in Europe.

4 And the reason why he stopped was that we
5 won the trial in 1995. —

6 And so the logic kind of breaks down that,
7 but for this infringement, we never would have gotten a
8 head start in Europe. We could have manufactured
9 outside the United States, and that's perfectly proper
10 and encouraged by the laws of other countries.

11 So I think the basic premise is -- really
12 isn't there, whereas, again, in a trade secret case, it
13 is there, because, by definition, when you steal a
14 trade secret and exploit the trade secret, you're
15 getting some kind of a head start from the trade secret
16 that you couldn't have gotten without the trade secret.
17 CellPro could have gotten the same head start by
18 manufacturing outside the United States, which they
19 would have if they had thought there was any reason to
20 do it. And, indeed, they did for a while.

21 MR. WARE: Yes. The interesting thing about
22 this argument is that CellPro has never actually told
23 us in opposing this injunction what they actually plan to
24 do, as far as foreign manufacturing and sales.

25 I believe what's going on is actually that

1 its business competitor has not seen fit to get himself
2 patent protection, such as in Europe.

3 I can't represent to the court that CellPro
4 right now, today, is starting manufacturing operations
5 in Europe. They may be. They may not be. I just
6 don't know the answer to that question. But they
7 certainly ought to be welcome to do it. And the
8 plaintiffs are proposing a form of injunction that
9 would prohibit them to do it, even though it wouldn't
10 be an infringing act if they did do it. That's my
11 problem.

12 THE COURT: All right.

13 MR. WARE: If we can move on to the stay...

14 THE COURT: All right.

15 MR. WARE: I think that, analytically, it
16 helps to sort of subdivide the stay into several areas.
17 One is United States versus the rest of the world and
18 what we have proposed is different in the United States
19 from in the rest of the world.

20 And the second is subdivision between
21 CellPro's commercial sales of its device for the rather
22 limited FDA approval, approved indication that it has
23 versus the clinical trials.

24 And then within the clinical trials,
25 there's really a subdivision as between clinical trials

1 that are ongoing and have been approved by the FDA, and
2 the applicable IRB, and clinical trials that simply
3 might be proposed at some point in the future.

4 I think, as to commercial sales in the United
5 States, there's not a whole lot that needs to be said,
6 except to come back in a few minutes to the issue of the
7 incremental profit payment on those sales. But I don't
8 think there's any serious objection to the scope of the
9 stay and the terms of the stay with respect to
10 commercial sales.

11 The thrust of CellPro's objections relates
12 to clinical trials. And as we have made clear in the
13 papers that we have filed, it was never the plaintiffs'
14 intention to preclude CellPro from continuing to supply
15 those clinicians who are engaged in FDA-approved
16 clinical trials.

17 We do believe, however, that there is no
18 reason why CellPro should be able to conduct clinical
19 trials indefinitely, that is to start new clinical
20 trials, because in that realm, there are two products
21 available to a clinician, neither of which currently
22 has FDA approval with respect to the particular uses
23 in the clinical trials.

24 If CellPro had FDA approval, they couldn't
25 be doing clinical trials. And so CellPro's device is

1 more disruptive to permit an infringer providing
2 infringing products.

3 The arguments presented by CellPro in
4 its filing last week are principally -- principally
5 amount to disparagement of Baxter's product.

6 And we have filed a motion to strike those
7 declarations. We do not think that it is proper for
8 the Court to consider ex-parte declarations filed
9 post-trial. Those deponents have never -- declarants
10 have never been deposed or cross-examined. They were
11 not identified in the pretrial order. The facts on
12 which they rely were not identified in the pretrial
13 order. And as the Shyley (phonetic) case indicates,
14 in a case involving Lyon & Lyon itself, this is not a
15 proper way to decide the scope of an injunction.

16 We have, nevertheless, submitted on behalf
17 of the plaintiffs some declarations on very short
18 notice, which I think makes clear that the Baxter device
19 is a -- is an entirely acceptable device that clinicians,
20 in fact, use. It's installed in more than 40 cites
21 around the United States and Canada, at some of the
22 most prestigious institutions, hospitals and other
23 institutions. Clinicians are very satisfied with it.
24 It works well.

25 In fact, it has comparisons -- in

1 every bit as much experimental in that particular
2 indication as is Baxter's.

3 And the concern here is that these are --
4 this is a situation where CellPro, if permitted to
5 continue forever doing these clinical trials with the
6 SC device, could make it extremely difficult for
7 Baxter to ever establish a market for a commercial
8 market, because I'm sure clinicians are quite content
9 to continue to receive supplies for free or at a very
10 reduced cost. And these are situations where there's
11 absolutely no reason why the clinician cannot specify
12 the Baxter Isolex device in a future trial.

13 So we are not proposing that they must
14 substitute the device in a current trial. But -- so
15 we think it's appropriate to draw that distinction.
16 And I think that, really, in terms of the public
17 interest, if anything, it is more disruptive, if
18 you're looking down the road to the future to a trial
19 that hasn't even been proposed to the FDA yet, that it
20 is really even more disruptive for the clinicians
21 themselves and the hospitals themselves to embark upon
22 clinical trials using a product that ultimately will
23 be enjoined from use.

24 And so, therefore, just as Judge Farnan
25 indicated in the Critikon case, it can be actually

1 comparisons with CellPro's device, it has been shown to
2 work, to provide better results and to be every bit as
3 easy to use, if not more so.

4 So the Court certainly should not deal
5 with this issue of a stay based upon the assumptions that
6 the plaintiffs or a licensed party under the patents has
7 nothing to offer that will address the medical need.

8 So what we have tried to do is we have tried
9 to craft a stay that will assure that there is no patient
10 who will be deprived of access to the inventions that
11 Dr. Civin made at Johns Hopkins University. But this
12 needs to be a transition period. It cannot go on
13 forever.

14 I anticipate from CellPro's papers that
15 the argument is now being asserted that as to the
16 clinical trials, that somehow the injunction can't cover
17 them because of Section 271(e). And I remind the Court
18 that, at the last hearing we had on March 13th, counsel
19 for plaintiff stood up and acknowledged that there was
20 no Section 271(e) in the -- defense in the case. It was
21 not raised by CellPro in the answer. It was not raised
22 in the pretrial order.

23 CellPro would have had to prove that the
24 particular supplies of products to institutions engaged
25 in clinical trials were actually exempt under Section

1 271(e). That's a burden that they did not undertake.
2 And, therefore, they cannot now complain that an
3 injunction will encompass sales or supply of products
4 that somehow they might have proven to be exempt under
5 Section 271(e).

6 In fact, as we indicated in our papers, we do
7 not think that they could have made that -- met that
8 burden of proof in any event, because that exemption is
9 a very narrow one that relates to uses that are solely --
10 solely for developing FDA information, and CellPro
11 certainly could not say when it makes the 12.8 antibody
12 that it is doing so solely for purposes of FDA reporting
13 requirements, because it has a commercial device. The
14 commercial device is on sale in the United States and
15 in Europe.

16 But, in any event, that issue simply is not
17 before the Court and it is a red herring.

18 I think that it might make sense to stop now.
19 I have some comments on the incremental profit and I have
20 a few more comments -- although I think we pretty much
21 covered the European sales issues. But I think I will
22 stop right now.

23 THE COURT: Okay.

24 MR. REILLY: Your Honor, if I may respond to
25 that, I think what counsel was alluding to for part of

1 sale or selling the SEPRATE SC except
2 for use in clinical trials meeting the
3 requirements of the exception stated
4 in," and then they cite 271(e)(1) and
5 271(e)(3).

6 So it certainly was in the issues that
7 were stated.

8 As to whether the parties were expected to
9 put in all their proof relevant to the injunction at
10 the trial, I would remind the Court of a couple of
11 things. The plaintiff successfully moved for an order
12 in limine, which forbade CellPro to do anything that
13 would intimate to the jury that there even might be an
14 injunction in this case.

15 So we couldn't very well put in all our
16 proof relevant to the injunction issue at the trial in
17 light of the motion in limine.

18 Furthermore, the injunction, proposed form of
19 injunction, was something we never saw until after the
20 trial, and all kinds of issues that it raises, such as
21 what would be the public health impacts, the impacts on
22 CellPro to have this \$2,000 per unit price, to have a
23 prospective two-year injunction in Europe, and a host
24 of other issues that pop out at you when you read the
25 proposed injunction, but not before, couldn't possibly

1 the time was the paper we recently received wherein
2 the plaintiffs have moved to strike our declarations
3 that deal with issues, including the 271(e)(1) issue.

4 As to the late service point, Mr. Ware didn't
5 get into it, and perhaps neither should I, but I
6 understand that the Fed Ex people failed to come and pick
7 up the declarations and get them to Boston on the night
8 when they were left for Fed Ex to get them.

9 Local counsel received them timely. Counsel
10 in Boston received them a day late. And to the extent
11 that there's any innuendo in the brief that this was
12 deliberate, I understand that Mr. Powers, our local
13 counsel, is prepared to explain how this all happened, if
14 the Court wants to hear about it.

15 As for the point about 271(e)(1) not being
16 in the pretrial order, it was in the pretrial order, and
17 the plaintiffs themselves put it there.

18 If one goes to plaintiffs' statement of
19 issue of law No. 9, which is found under Pages 9 -- at
20 Pages 9 and 10 under Tab 3 of the pretrial order, they
21 frame the injunction issue thus:

22 Quote, "Whether plaintiffs are
23 entitled to an injunction prohibiting
24 CellPro" -- "CellPro from importing,
25 exporting, making, using, offering for

1 have been fairly expected to have been addressed at
2 trial.

3 And I think the last time the Court really
4 went on record as to what it expected to be done about
5 the injunction and how it saw this issue being handled
6 was at a hearing. Before the last trial -- I have a
7 February 21st, 1995 transcript and at Page 29 of that,
8 Lines 2 through 14, the Court said, and again I'm
9 quoting:

10 "Here's what I think I will do.

11 I am generally familiar with the case
12 law that talks about situations where
13 a Court may not grant an injunction
14 because of the public interest in having
15 health care products on the market. I
16 think what I will do is simply defer the
17 discovery on that. If we get a jury
18 verdict, and the plaintiffs pop up and
19 say, Judge, enter an injunction today, we
20 can then have a discussion about what
21 further information CellPro may want in
22 order to oppose the entry of an injunction
23 at that point. We may know at that point
24 where the FDA is on these products."

25 And your Honor goes on with other comments

1 along those lines.

2 I think it's pretty clear from that -- and
3 we certainly understood -- that the court contemplated
4 some separate determination preceded by discovery of
5 some kind on the exact form and scope that any
6 injunction might take. That's a fair way to handle it.
7 That's how we thought it would happen. That is how we
8 expected it to happen.

9 And, indeed, it is really the only way that
10 it can happen, given the order in limine that prevented
11 any kind of meaningful ventilation of the injunction
12 issues during the jury trial.

13 And when we weren't yet on notice of the
14 proposed injunction, the details of the proposed
15 injunction they would seek. And a lot of very
16 important objections go to those details.

17 So that answers their motion to strike the
18 declarations. I think the declarations are fairly in
19 the case.

20 Now, if I may move on to the substance of
21 it, counsel calls the 271(e)(1) issue a red herring. It
22 is not, for several reasons. The most fundamental of
23 them is the 271(e)(1), when you read it together with
24 271(e)(3), imposes an explicit limitation on judicial
25 power. (e)(3) says no injunction, or other relief,

1 may be granted which would prohibit the making, using,
2 selling or offering to sell in the United States a
3 patented invention solely for reasons related to FDA
4 approval.

5 It's kind of a rare thing, I think, in
6 federal statutes where you have one section saying the
7 Court can issue injunctions and then you have a separate
8 and more specific section saying the injunction may not
9 forbid this.

10 So it's -- patent rights are creatures of
11 statute and the remedies that can be granted are
12 limited by statute. And in this case Congress has
13 determined that it simply is not an act of infringement
14 to use someone's patented technology for purposes of
15 getting your FDA approvals ready.

16 For that reason, it would, I think, be --
17 it would be violative of 271(e)(3) if the Court were to
18 enter the injunction in the form that plaintiffs
19 request, because as long as something is a bona fide
20 FDA study that is aimed at either what is called a
21 label expansion, to get an approval to sell the device
22 and advertise it for another use, another indication, or
23 a new device approval -- and CellPro, as we point out
24 in our declarations, has some second-generation devices
25 that would combine the use of the 12.8 antibody to

1 enrich the stem cells with the use of other antibody to
2 enrich or deplete for other kinds of cells. And those
3 are being FDA tested right now.

4 And under 271(e)(1), CellPro has a perfect
5 right prospectively to do that.

6 To counsel's point that we somehow waived the
7 right to rely on 271(e) by not asserting it as a damage
8 defense, I think that view misapprehends the difference
9 between prospective remedies and retrospective remedies.

10 Damages is a retrospective remedy. That's
11 for what you've already done. And from the fact that
12 CellPro chose not to argue that a portion of its past
13 sales were FDA exempt should in no way foreclose CellPro
14 from arguing that if, in the future, it wants to do
15 things that are FDA exempt, it can.

16 The prospective aspect of this has nothing
17 to do with the retrospective aspect of it. On the face
18 of their own statement of issues of law, the plaintiffs
19 acknowledge that 271(e) is the immovable object here.
20 An injunction that does not make allowance for 271(e)
21 exempt uses is an injunction that is on its face
22 overbroad and I think unlawful.

23 I just don't think that the Court could sign
24 it in the form in which plaintiffs propose it without
25 running afoul of two 71.

1 Now, just what is a 271(e)(1) exempt use is
2 something that can be debated later. But an injunction
3 that says you can't make any uses that -- that says you
4 may make uses that are 271(e)(1) exempt is certainly,
5 I think, what it would have to say. The injunction
6 would have to carve out that exception if an injunction
7 were entered at all.

8 And the fact that CellPro has a commercial
9 product I don't think is sufficient as a matter of law
10 to support a conclusion that there can be no conceivable
11 use of that product that would be exempt.

12 We have in approximately 20 of our
13 clinicians' declarations and also in the declaration of
14 Dr. Cindy Jacobs, who's CellPro's Director of Clinical
15 Research, we talk about a number of studies that are
16 going on, 50 or 60, I think, in the United States alone
17 at this point, and in some Europe that are under IDE's
18 and are for the purpose of gathering data to either do
19 a label expansion or to get a new device approval.

20 ---
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22
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25

1
2 MR. REILLY (Continuing): Those are not
3 commercial sales. They can be made at a commercial
4 price. There is an FDA regulation and it is Mr. David
5 Weed's declaration that gets into this. He is the
6 person who is the former Deputy Counsel, I think, of the
7 FDA. He explains that when you supply medical devices
8 in support of a clinical trial, you can sell them at
9 retail. You can at most charge only a cost recovery
10 price.

11 ---

1 to drawing the line at present -- presently under way
2 trials. Under the law, it simply is not an act of
3 infringement, and it cannot be enjoined if a company uses
4 the patented technology to seek FDA approvals.

5 This was debated in Congress and the
6 plaintiffs' side lost on that question. It's simply
7 exempt and you can't read it out of the law. It is a
8 limitation on judicial power.

9 One more point that I wanted to make on that.
10 Just on the point of why the injunction will be overbroad
11 on its face if it failed to make allowance for 271(e)(1)
12 exempt activities, there are a number of things that
13 CellPro would have to do to support its FDA trials,
14 whether it was making a commercial product in the
15 United States or not.

16 And, as I understand the injunction, it would
17 prevent CellPro, at least after Baxter got an FDA or some
18 licensee got an FDA approval, from even using the CellPro
19 device for its one approved application, which is bone
20 marrow transplantation for breast cancer.

21 If that use were enjoined, then just about
22 everything else that CellPro would be doing would be in
23 support of some kind of an IDE.

24 As for the notion that CellPro could somehow
25 go hog wild and just do some unlimited number of clinical

1
2 MR. REILLY (Continuing): And as Dr.
3 Jacobs' declaration explains, some of the doctors expect
4 reduced-priced goods or they won't participate in trials
5 and some of the patients can't afford it unless the
6 devices are supplied cheaper or free.

7 Now, I think Mr. Ware has basically conceded
8 that point. I see that his revised form of injunction,
9 at least for present clinical trials, that is once
10 already under way, would exempt from this \$2,000 per
11 unit sold royalty rate any CellPro disposables that
12 are supplied in connection with these FDA trials.

13 I think that is correct, and that's how it
14 has to be. I think anything else would run afoul of
15 271(e)(1).

16 So the main point, your Honor, is that a
17 large amount of the uses of the CellPro device that are
18 going on presently are in support of -- either CellPro-
19 sponsored or investigator-sponsored investigational
20 device exempt uses that have been cleared with the FDA,
21 and these are uses being made for the purpose of
22 either getting a label expansion or getting a new
23 device approval, and it's exactly what 271(e)(1)
24 permits.

25 There's absolutely no basis in law or in logic

1 trials for some bad-faith reason, I think the best answer
2 to that is that's a problem for the FDA; it's not a
3 problem for this Court.

4 And the FDA has ways to deal with that.
5 Again, I would refer the Court to Mr. Wida's declaration,
6 which I think makes the point, and Dr. Jacobs' does also:
7 That the FDA does not let you use clinical trials just to
8 get out there and do commercial distribution. They won't
9 let you charge a commercial price. They won't let you
10 test market. They won't let you advertise the product
11 for that use. And they want to know that it's real
12 science that you are doing, and they want to see your
13 protocol.

14 And once you have your IDE, you'd better
15 not depart from the protocol. You'd better treat only
16 the patients who say you'll treat and only the way you'll
17 say you'll treat them, and you'd better also comply with
18 all the reporting and data-gathering requirements,
19 because the purpose of an IDE is not to be some kind of
20 a blind for commercial sales.

21 And, in fact, the FDA can, and does, revoke
22 IDE permissions if it sees someone is using them as a
23 blind for commercialization. I think that's something
24 the FDA can police and this Court does not have to.

25 MR. WARE: It seems like this is a good

1 moment to jump in.

2 MR. REILLY: I think it is.

3 THE COURT: All right.

4 MR. WARE: Okay. Well, several comments.

5 First, as a sort of procedural posture, I
6 think at the time the statement in the pretrial order
7 that counsel referred to was done, I think that
8 plaintiffs thought that perhaps it was CellPro's
9 intention to raise this. But they did not. They made
10 it clear they were not.

11 They even provided, with respect to damages,
12 they provided a statement of all of the revenue received
13 from SC - the SC device, which quite explicitly included
14 the cost of recovery sales as well, and did not assert a
15 271(e) defense.

16 Mr. Reilly suggested that, while there's a
17 big difference between damages and a future injunction,
18 but what they actually did was they did not assert the
19 defense as to liability either. And that statement is
20 actually made in a brief that was filed in this court
21 on March 13th, 1997. And we cite it in our brief.

22 They stated, We have not asserted a 271(e)
23 defense to liability or damages.

24 If you are going to take the position that
25 particular sales and uses of your product are

1 noninfringing by reason of 271(e), you would be asserting
2 a defense to liability. That defense was not asserted,
3 so that -- so that all of the types of trials that are
4 going on now were treated by CellPro as no different from
5 the commercial sales, and there simply is no basis, legal
6 or factual, in the circumstances to then take the
7 position that, well, all those sales are noninfringing
8 under 271(e) and, therefore, the Court can't enter an
9 injunction.

10 The approach that Mr. Reilly is suggesting is
11 one that the Federal Circuit has said is improper. In
12 the Eli Lilly V. Medtronic case, or one of the Eli Lilly
13 versus Medtronic cases, which we cite in our brief, the
14 Court said that you don't just -- you don't enter an
15 injunction that says that it's subject to whatever
16 271(e) exemption there might be. That is an issue --
17 that's a liability issue. And so that the defendant
18 has to actually prove that particular sales are sales
19 that are noninfringing under 271(e).

20 So if that does not happen, they get
21 enjoined. Those sales have been found to be infringing
22 sales.

23 There was no exception in the Court's
24 determination that CellPro was infringing for any
25 particular types of sales. They are all infringing and

1 they should all be subject to the injunction.

2 It is also not enough to simply recite the
3 phrase clinical trial and say that they're exempt. There
4 is a serious factual issue about the 271(e) exemption
5 because of the use of the phrase "solely" in the statute,
6 which would be read out of it entirely under Mr. Reilly's
7 argument.

8 So that there are real issues that would have
9 to actually have been presented and tried to -- for
10 CellPro to establish that certain types of sales were
11 noninfringing and protected under Section 271(e).

12 The suggestion that certain sales or uses of
13 the device must be for 271(e) purposes, because they're
14 being used in clinical trials, overlooks the fact that
15 that isn't the point -- or that's certainly not the first
16 point, when CellPro has infringed. CellPro has
17 infringed the '204 patent when it has made the 12.8
18 antibody. And when it makes the 12.8 antibody, it
19 certainly cannot say that its infringement at is solely
20 for seeking FDA approval.

21 But that defense is not in the case and it
22 certainly was never contemplated in the pretrial order
23 and it certainly was never discussed with this Court
24 before the trial in March that we were then going to have
25 another trial after the completion of that trial at which

1 there would then be testimony and evidence presented in
2 order to establish a 271(e) defense that would go to the
3 scope of the injunction. That was never discussed, never
4 contemplated. And CellPro made its choice when it decided
5 not to raise a 271(e) defense.

6 I think it recognized that it would have a
7 very difficult time establishing a 271(e) defense, and it
8 did not choose to do that.

9 THE COURT: Why? Why would it have a
10 difficult time?

11 MR. WARE: Because of the "solely" language
12 in the statute. It is -- there is only an exemption
13 where the infringement that is done is infringement
14 solely for purposes of meeting FDA requirements. And
15 that simply is not the case here, because they have --
16 they make the 12.8 antibody for all kinds of purposes
17 and uses which have nothing to do with FDA approval;
18 i.e., selling the product commercially in the United
19 States and in Europe.

20 So -- but, in any event, it's a question
21 of fact. It's one that has to be determined as a
22 liability question. And if a party does not raise it,
23 they are not entitled to come in afterwards and raise
24 it. And they are not entitled, then, to -- when an
25 injunction is entered, to then say, Well, now, every

1 time that we're accused of violating the injunction, we
2 have to come in and have a factual determination of
3 whether or not that particular activity was infringing
4 because of 271(e).

5 That's exactly what the Federal Circuit said
6 they did not want to have happen and that issues that go
7 to liability of whether a party is infringing or is
8 exempt from infringement under 271(e), that's supposed to
9 be tried as part of liability. And if a party waives
10 that defense, it is not in the case.

11 As far as the future trials, too, the other
12 thing I wanted to suggest is -- I mean, the point of --
13 to the extent that there -- let me back up.

14 The point of the statute was to -- to allow
15 a certain -- certain activities sort of in the period
16 before the patent expired. We're talking about a patent
17 that expires ten years from now. And clinical trials
18 that CellPro might start at this time are certainly not
19 ones that are designed to put it in a position to offer
20 a product when the patent expires.

21 And there is a serious disruption and harm
22 to Baxter by permitting CellPro, in effect, to just
23 indefinitely engage in clinical trials.

24 And so that's why we're talking about an
25 injunction that the -- the injunction on its face would

1 cover all of these activities. We're then talking about
2 the scope of the stay from that injunction. And we do
3 not think that the Court is required, or should enter
4 such a broad stay as to really eliminate for the next
5 ten years any serious effect of the permanent injunction.

6 So that's a different -- that's the
7 difference there.

8 One other thing I wanted to say, I was pleased
9 to hear actually Mr. Reilly's comment about the
10 limitations on the approved use of the CellPro product
11 and his acknowledgment that offering that product for
12 uses other than the limited approved use that he referred
13 to is improper.

14 A considerable amount of time was --
15 considerable amount of space in CellPro's declarations
16 that it filed and in its opposing brief were devoted to
17 the argument that, because CellPro had an approved
18 product, that somehow that made it much more appropriate
19 than the Baxter product, even for uses that were not the
20 approved uses.

21 And that argument runs directly into the
22 FDA's very strict limitation on what an approved use is.
23 And anything other than what the FDA has authorized as
24 the approved use is an experimental use as to which no
25 decision has been made by the FDA as to whether it is

1 safe and effective for that use. It's still
2 experimental.

3 And so, as we pointed out in our papers, for
4 those clinical trials, the Baxter product and the
5 CellPro product are both in the same boat.

6 Something came across my desk yesterday that
7 I would like to bring to the Court's attention, because
8 it relates to this very argument that CellPro made, that
9 its own FDA approval gives it some special availability
10 to clinicians. And this is a letter that I was unaware
11 of until yesterday that was written to CellPro by the
12 FDA earlier this year that is highly critical of
13 CellPro's actions in promoting its product to doctors
14 for other than its approved use.

15 And it actually told CellPro that what it
16 was doing was misbranding the product, that it was
17 making misrepresentations about the product, that it
18 was making statements that are regarded by the FDA to
19 be false and misleading.

20 And I would like to submit that to the
21 Court (handing document to the court).

22 THE COURT: Do you want to identify the date
23 and author?

24 MR. WARE: Yes.

25 MR. REILLY: Your Honor, I would object to it,

1 first for lack of notice, and, secondly, as irrelevant to
2 any question that's before the Court.

3 (Mr. Ware handed document to Mr. Reilly.)

4 MR. WARE: Just for the record, this is a
5 letter -- I can't read the date. It appears to be
6 January something, 1987. And just so there's no
7 mystery about where --

8 THE COURT: '97?

9 MR. WARE: 1997. January 1997 from the FDA
10 to Monica Krieger of CellPro. She is the chief
11 regulatory person. This letter was sent to Baxter's
12 Law Department anonymously from someone at CellPro who
13 evidently believed that the conduct of CellPro in this
14 regard was, indeed, inappropriate. And I just learned
15 of this letter yesterday.

16 But I think that that should be in the record
17 because I think that the record presents a very
18 misleading argument with respect to the -- the
19 availability of the CellPro device to be used for so-
20 called off-label purposes. That appears in several of
21 the declarations, including Mr. Wida's declaration, I
22 believe.

23 And so from the FDA's perspective, that's not
24 the case. It's not appropriate. And so any such use
25 needs to be under an authorized IDE, just as does

1 currently any use of the Baxter device.

2 And so that's -- that's why, I think, that it
3 is important, as we look down the road towards future
4 clinical trials, to recognize that these are two products,
5 either one of which can be specified by a clinician for
6 a clinical trial, and that there is -- there is no public
7 health concern of the nature raised by CellPro with
8 respect to its current clinical trials when we are
9 focusing on the future.

10 So I think what I would -- I think it would
11 make sense to turn to a few comments about the
12 incremental profit calculation.

13 MR. REILLY: If I may just respond to some
14 of these points briefly...

15 This letter, your Honor, as I understand it,
16 CellPro put around a Christmas card. They had on it a
17 drawing by some little child whose life had been saved
18 by the CellPro device. And there was a little
19 biographical blurb about the kid on the back of the
20 Christmas card that said what the child had been
21 successfully treated for. And it was off-label use. And
22 the FDA felt that that was inappropriate.

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2 MR. REILLY (Continuing): As I understand it,
3 just because I think the record is in a very confusing
4 state about this.

5 Off-label use is something that the FDA does
6 not control. Advertising of a medical product in
7 interstate commerce for an off-label use is something
8 that the FDA controls. The FDA does not, however,
9 regulate the practice of medicine.

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2 MR. REILLY (Continuing): And once a device
3 is FDA-approved for one indication, it may be sold in
4 interstate commerce.

5 Once it is sold in interstate commerce,
6 any physician within the bounds of state law and
7 professional ethics may make the judgment that it ought
8 to be used to treat a certain patient in a certain way,
9 as long as it's not advertised for that use, as long as
10 the doctor doesn't basically proceed on other than an
11 one-by-one medical judgment basis. Off-label uses are
12 permitted.

13 And I would refer the Court to the
14 declaration of Mr. Wida, the former Deputy Counsel of
15 the FDA. Paragraph 7, specifically, talks about
16 off-label uses. And it says, off-label uses are
17 allowed. And they're quite common. The difference is
18 if you have an unapproved device that's not approved for
19 any indication, it may not move in interstate commerce
20 for the treatment of human patients at all, except as
21 part of a clinical trial.

22 So that physicians are relatively free to --
23 for humanitarian reasons, make an off-label use of an
24 FDA-approved device on a particular patient in
25 particular circumstances. The FDA does not disapprove

1 that. They would disapprove it if he advertised that
2 he was doing that.

3 But that's where it goes. And I mean that's
4 where it stops. And so there is a significant advantage
5 to having a device that's FDA-approved from one
6 indication. And, in fact, we have among our declarations
7 Dr. Wida's -- Mr. Wida's declaration explains at great
8 length why it is that the idea that Baxter, with just a
9 patchwork quilt of IDE's and no FDA approval for any
10 indication, cannot fill the gap in patient care
11 availability.

12 That would happen if the CellPro device were
13 frozen at the number of columns that CellPro had in use
14 as of March 12, which is what their injunction proposes.
15 That March 12 date is a scant three months after CellPro
16 got its FDA approval.

17 I think there is something like 50 or 60
18 sites in the United States that have CellPro devices
19 right now. And there are a lot more cancer patients
20 and a lot more places than that.

21 So this business about off-label use and
22 whether Baxter and CellPro are in the same boat, other
23 than for the indicated use, I think is an important thing
24 to dwell on for a moment, because it is just absolutely
25 infeasible that Baxter, without an FDA approval, could

1 completely satisfy the needs of patients for treatment.
2 There are very, very significant constraints
3 on the ability of physicians to make choices in patient
4 treatment when they've got only an unapproved device to
5 work with.

6 Several of our declarants make the point
7 that off-label use is a big -- a big advantage. Ease
8 of recruitment of patients is an advantage of having
9 a -- an FDA-approved device.

10 Ease of getting insurance reimbursement
11 without which some patients couldn't be treated is --
12 is something that's mentioned by Dr. Anderson and also
13 by Dr. Sender in his declaration, and also by Mr. Wida.

14 The ease of getting new IDE's approved, if
15 your device has already been found safe and effective
16 for one application, is quite significant. I think
17 eight or nine of our clinician declarants have remarked
18 on the fact that it's easier to get IDE's approved in
19 your institutional review board and your hospital,
20 university, and also by the FDA, if you can say this has
21 been found safe and effective by the FDA for at least
22 this one application.

23 So the point of all this, and I think Mr.
24 Ware has gotten -- fairly gotten into it by this
25 letter -- the point of it is that you just can't -- it

1 is unrealistic to think, it is totally impractical to
2 think, that if CellPro remained frozen at the number of
3 devices and places in the United States as of March
4 12th, that Baxter, with no FDA approval, could go in
5 there and completely fill the market.

6 It can't. It cannot sell its device
7 commercially. It cannot advertise its device. And IDE's
8 are not -- they are not a stopgap for commercial sales.
9 I think Mr. Wida's declaration makes that very, very
10 clear. There would be a shortfall in filling the needs
11 of patients for care if -- if CellPro were frozen at
12 the number of devices it's now got in place.

13 MR. WARE: There's just a couple of brief
14 points.

15 CellPro actually provided us no data at all
16 about the number of sites they were in. And I think
17 that it is entirely conjecture on the part of Mr.
18 Reilly's part that those sites cannot somehow fill the
19 needs for patient care.

20 Bone marrow transplants aren't performed in
21 every little local hospital. They are performed in
22 transplant centers. And it's not clear to me that there
23 are even are a whole lot more transplant centers in the
24 United States, which is one reason I think there was
25 essentially no comment on this issue in CellPro's

1 briefing. I don't think that's a real issue, as far as
2 the commercial sales.

3 And as far as everything else that CellPro
4 is talking about, they are talking about their own uses
5 of their product under IDE's, not under approved
6 usage -- uses, and in areas where the -- the FDA has
7 not concluded that CellPro's device is safe and effective
8 for use.

9 So I think we're just, you know, we're
10 talking about IDE situations that -- I mean, that's
11 what we're talking about when we're talking about the
12 stay. This off-label use is -- I think our point is this
13 is not something -- this is not a basis on which the
14 Court should tailor the stay of the injunction in order
15 to specially encourage off-label use of CellPro's
16 product, because it's something that, while the FDA may
17 not have the authority to regulate on individual doctors'
18 use of it, it certainly does disapprove of it, and that's
19 not a good basis for an injunction or a stay of an
20 injunction, to encourage that.

21 THE COURT: Stop just for a minute. I need
22 to take a break or stop.

23 How much longer do you think you'll be?

24 MR. WARE: Very short. I think, really, the
25 last thing that I wanted to address very shortly was

1 just the incremental profit point.

2 THE COURT: All right. Why don't we talk
3 about that real quick, then I'm going to need to go.

4 MR. WARE: Okay.

5 THE COURT: If anybody has to say anything
6 they want to say, feel free to write me.

7 MR. WARE: I think, first of all, just
8 conceptually, it's important to underscore our point
9 here, which is that anything other than payment to the
10 plaintiffs of incremental profit allows CellPro to
11 benefit from its willful infringement, and we don't
12 think that should be permitted.

13 So I think what the -- so I think the
14 concept is entirely appropriate, and I have not really
15 heard much argument from CellPro as to why it isn't.

16 What we're mostly arguing about here is the
17 floor that we proposed simply to avoid all of the kinds
18 of -- all of the kinds of accounting games that can be
19 played once you give somebody the ability to calculate
20 their incremental profit.

21 And I am sure CellPro would, if we had no
22 floor at all, it's quite clear from Mr. Simpson's
23 affidavit, that they would say we lose money on every
24 sale but I guess hope to make it up with the volume.

25 And I think beyond that, what I'd like to

1 do is -- do you want very briefly -- there are just a
2 couple -- there are a few things that we just picked up
3 that are I think just worth mentioning, although if the
4 Court prefer that we do it by letter, we can. But they
5 have to do with the calculations that Mr. Simpson did.
6 And I think we can show the Court why those calculations
7 are so off base that they should not be considered at
8 all as a basis for establishing a floor for this -- for
9 this incremental profit calculation.

10 But if the Court would prefer that we do that
11 in writing, we can do that.

12 THE COURT: Realistically, what will happen is
13 I will go back and reread the transcript of what was said,
14 when I've got Simpson in mind and exactly what went on
15 with it. It may be just as easy for you to read the
16 letter. I've got another argument coming up at 2:00
17 that I need to get focused on.

18 So if you don't mind, I'm happy to have you
19 write a supplemental paper, if you don't mind. I'd just
20 as soon get it done that way, if that's all right.

21 MR. WARE: Yes.

22 THE COURT: I saw you all carrying a disk
23 around. I take it that's probably a disk of the order
24 of the form of injunction?

25 MR. WARE: Would that be helpful?

1 conversations with Mr. Culver, who is the CFO of -- the
2 CFO of CellPro.

3 Now, if we, so to speak, criticize the
4 Simpson declaration, which it is very -- incidentally,
5 very easy to do, then they will come back. They'll
6 play around with the figures again. We still won't have
7 the figures that they are relying on.

8 The only point we are trying to make, your
9 Honor, is -- in that letter -- and it's already addressed
10 in part in Dr. Hausman's declaration, which had to be
11 prepared. We only got their papers last week. Is that
12 the figures are not trustworthy because they are very
13 selective.

14 For example, they are loading an entire
15 year's worth of manufacturing costs and selling costs
16 into a year when they only had partial revenues in the
17 U.S.. They're comparing apples and oranges.

18 They're also loading the entire costs of
19 making all 12.8 profits, including the big devices
20 themselves, on to the cost of the disposable units.
21 But these are issues we can point out. Simply to say
22 the Court shouldn't rely on them, but I don't think
23 they should now be offered an opportunity, so to speak,
24 to fix what Mr. Simpson has done while still depriving
25 us of the information on which he is relying.

1 THE COURT: There's no harm in passing it
2 up.

3 MR. BLOOMBERG: I have two very brief
4 points, your Honor, one with respect to misuse.

5 THE COURT: Sure.

6 MR. BLOOMBERG: Will we be allowed to take
7 discovery on that topic, your Honor?

8 THE COURT: I think what I am going to do is
9 have plaintiffs file their motion for summary judgment,
10 stay discovery on it, and then during the briefing, if
11 you can identify for me what facts you believe you
12 would obtain during discovery as you would under Rule 56,
13 in any event. And then we'll see where we are.

14 MR. BLOOMBERG: Fine.

15 And the last point, once we see the letter
16 that they are submitting with respect to Mr. Simpson, may
17 we file some response if we think it's appropriate?

18 MR. ELLIS: Your Honor, I don't think that's
19 quite fair, because they elected to file Mr. Simpson's
20 declaration without disclosing the documents from which
21 Mr. Simpson extrapolated his data.

22 Mr. Simpson's declaration is arrangement of
23 figures that are taken from what is described as
24 unaudited financial statements of CellPro that have not
25 been provided to us. And based on undisclosed hearsay

1 THE COURT: All right.

2 MR. REILLY: Your Honor, I think what
3 probably would be appropriate would be some discovery on
4 the question of whether the injunction -- and if it were
5 not stayed, would bust CellPro. I think the issue is
6 actually broader than that.

7 There was nothing stealth or sneaky about
8 Mr. Simpson's declaration. The reason why it had to be
9 put together on such short notice is that this \$2,000
10 per unit figure that the plaintiffs came up with and
11 put in their proposed injunction was something never
12 mentioned at trial, never put in the pretrial order,
13 and seemed to be kind of picked out of the air.

14 And I think, really, there's a broader issue
15 here as to whether the terms of the injunction would
16 shut down CellPro. And it goes beyond the \$2,000 per
17 item. And I would think if we're going to go any
18 farther with this, there probably ought to be a hearing
19 on the economic impact. And you cannot really talk
20 about that until you know what the scope of the
21 injunction is going to be.

22 MR. WARE: Well, our view is that that
23 hearing was today, and we are not inclined to continue
24 this indefinitely. We've made a suggestion to the
25 Court. They've had their chance to respond to it. We

1 hope that the Court will take our views into
2 consideration and we're anxious to have the Court
3 resolve the issue.

4 THE COURT: Well, back to the question, if
5 you all are going to submit a paper on Simpson, then
6 they can respond.

7 If you are not going to submit something,
8 then I will just let the record sit the way it is,
9 unless somebody tries to lob something in.

10 MR. WARE: Then let me say this: I think
11 that Dr. Hausman's affidavit adequately sets out our
12 points, if I can add one more simply, which is that as
13 we looked at their all calculations today, this morning,
14 what we saw is that when they calculated the per-unit
15 costs of the disposables, they did it based on sales,
16 or based on manufacturing something like 4600 units.

17 They actually sold and compared it to about
18 2300 units. So they figured out the cost of making and
19 building an inventory for twice the number of product
20 that they actually sold and then they said that that is
21 the per-unit cost that should be considered.

22 So that's one point we wanted to add to what
23 we said before. But, unless I'm mistaken, I'll speak with
24 Mr. Ellis. I think probably we were going to underscore
25 points that are in Dr. Hausman's affidavit and it's

1 (Court recessed at 12:37 p.m.)

2 - - -

1 probably not necessary to go into it further.

2 THE COURT: Well, actually, what I was also
3 going to say is it may not be something that anybody
4 wants to hear. I see the injunction as an equitable
5 remedy and a remedy where I have to try to get it right.
6 And if somebody shows me today, next year, two years from
7 now that it's not right, I may have to keep tinkering
8 with it and until I do it.

9 And if it means I enter an injunction that
10 misses the target a little bit and I go back and re-do
11 it later, I'll go back and re-do it later. And I may
12 appoint somebody to go back out and give me some
13 accurate numbers and have them do it.

14 But we'll see.

15 MR. WARE: Thank you very much, your Honor.

16 THE COURT: All right. I think what's going
17 to happen is the next thing I will see is a motion for
18 summary judgment on patent misuse and I will get working
19 on issues on my plate, including enhance -- enhancement
20 of damages, attorneys' fees and nature of the injunction.

21 And when I receive the briefing on misuse, I
22 take it one of the things I'll see is whether there needs
23 to be evidentiary discovery on this subject or whether I
24 can resolve it without further discovery.

25 (Counsel respond "Thank you, your Honor.")

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